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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,374	07/11/2001	Steve A. Herweck	ATA-297	8317

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[REDACTED] EXAMINER

MATHEW, FENN C

ART UNIT	PAPER NUMBER
3764	

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/903,374	HERWECK ET AL. 
	<b>Examiner</b>	<b>Art Unit</b>
	Fenn Mathew	3764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 19 November 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1-12 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### **Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    - 1) Certified copies of the priority documents have been received.
    - 2) Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    - 3) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### **Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 6, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Tu et al. (U.S. Patent No. 5,061,276). Tu discloses a prosthesis comprising a first tube of polymeric material, a membrane of polymer material positioned about the exterior surface of the first tube, and a support structure wound along a winding axis about an exterior surface of the membrane (column 5, lines 25-45), to form axially spaced ridges that enable the material to substantially close a hole that is created when the material is punctured, the membrane having a microstructure of nodes interconnected by fibrils effective to facilitate bonding (column 7, lines 5-20).

3. Referring to claim 6, Tu discloses the nodes being perpendicular to the direction of expansion. Inherently the nodes are oriented at an angle other than 0 degrees with respect to the wound support structure. (Column 8, lines 20-26).

4. Referring to claim 11, Tu discloses a prosthesis comprising an inner tube of polymer material having an exterior surface, a membrane of polymer material positioned about the exterior surface of the inner tube, and at least one support structure wound along a winding axis about an exterior surface of the membrane to form axially spaced-apart ridges on the membrane that enable the material to substantially close a hole that

is created when the material is punctured, the membrane having a microstructure of nodes interconnected by fibrils, the nodes inherently being oriented at an angle relative to the winding axis effective to facilitate bonding of the support structure to the membrane.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4, 7, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. (U.S. Patent No. 5,016,276). Referring to claim 4, Tu discloses the claimed invention including ridges (inherently formed by support structure) spaced apart at a distance effective to direct a needle to a puncture site. The feature of having the spaced apart distance being less than or equal to 1.5 times the outer diameter of the needle is a design consideration within the realm of one with ordinary skill in the art.

7. Referring to claim 7, Tu discloses the claimed invention except for the specific angle of the nodes with respect to the winding axis. The feature of having the nodes at a 90 degree angle with respect to the winding axis would be a matter of obvious design choice within the realm of one with ordinary skill in the art, as applicant has not provided evidence that the stated angle provides any advantage, nor that any unexpected result would arise from the configuration disclosed by Tu.

8. Referring to claim 12, Tu discloses a method of making a prosthesis comprising the steps of providing a first tube of biologically compatible material, positioning a membrane of polymer material about the exterior surface of the first tube, and winding at least one support structure along a winding axis about the membrane, capable of enabling the material to substantially close a hole, the membrane having a microstructure of nodes interconnected by fibrils effective to facilitate bonding of the support structure to the membrane and inhibit delamination (column 15, lines 20-30) of the support structure from the membrane. The feature of having the spaced apart distance of the ridges being less than or equal to 1.5 times the outer diameter of the needle is a matter of obvious design choice within the realm of one with ordinary skill in the art as it would be necessary to inhibit tearing of the membrane.

9. Claims 2-3, 5, and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. (U.S. Patent No. 5,016,276) in view of Martakos et al. (U.S. Patent No. 5,897,587). Referring to claim 2, Tu discloses the claimed invention except for the specific material of the support structure. The feature of having the support structure made of a metal wire is a design consideration within the level of one with ordinary skill in the art, as evidenced by Martakos, who teaches an analogous device wherein the support structure comprises a metal wire. (Column 6, lines 34-35).

10. Referring to claim 3, Tu discloses the claimed invention except for a support covering. Martakos discloses an analogous device having a support covering (30). It would have been obvious to one having ordinary skill in the art at the time of invention

to provide the invention of Tu with a support covering as taught by Martakos in order to provide a protective covering.

11. Referring to claim 5, Tu discloses the claimed invention except for coalescing the first and second tubes and support structure. Martakos teaches an analogous device, and further teaches coalescing the recited structures using heat (claim 5). It would have been obvious to one having ordinary skill in the art at the time of invention to coalesce the recited structures with heat as taught by Martakos in order to facilitate bonding between the structures.

12. Referring to claims 8-9, Tu discloses the claimed invention including a membrane formed from a polymer material having a microstructure of nodes interconnected by fibrils with a porosity that is less than that of the first tube. Tu is silent with regards to the size of the nodes of the membrane compared to the first tube. Martakos discloses an analogous device and discloses the nodes of the membrane being smaller than the nodes of the first tube, and specifically that the nodes of the membrane are at least 10% smaller than the nodes forming the first tube. (Column 3, lines 4-10). It would have been obvious to one having ordinary skill in the art at the time of invention to have the nodes of the membrane be smaller than the nodes of the first tube in order to provide a lower porosity for the membrane.

13. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. (U.S. Patent No. 5,061,276) in view of Inoue (U.S. Patent No. 5,976,179). Tu discloses the claimed structure (see paragraphs above), except for the plurality of rings that make up the support structure. Inoue teaches an analogous device with rings (12) serving as

the support structure. It would have been obvious to one having ordinary skill in the art at the time of invention to substitute the support structure comprising at least two rings, as taught by Inoue for the helically wound support structure disclosed by Tu in order to provide a support structure that inhabits a smaller area of the prosthesis.

### ***Response to Arguments***

14. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection. Tu et al. discloses a support structure wound along the exterior of a membrane, as well as a microstructure of nodes and fibrils that facilitate bonding and inhibit delamination.

### ***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Golds            U.S. Patent No. 6,312,458

Lentz et al.    U.S. Patent No. 6,080,198

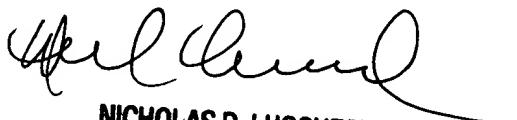
16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fenn Mathew whose telephone number is (703) 305-2846. The examiner can normally be reached on Monday - Friday 9:00am - 5:30pm.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.



NICHOLAS D. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
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February 19, 2003